K100096

Linac Collimator Assembly Housing (LCAH)
510(k) Summary

APR 22 2010

Submitter's name and address:
Integra Radionics, Inc.
22 Terry Avenue
Burlington, MA 01803 USA

Contact person and telephone number:
Helder A. Sousa
Regulatory Affairs Project Manager
Integra Radionics, Inc.
22 Terry Avenue
Burlington, MA 01803 USA
Phone: (781) 565-1235
Fax: (781) 238-0645

Date prepared:

December 11, 2009

Name of device:

Trade Name:	Linac Collimator Assembly Housing (LCAH)
Common Name:	Collimator Assembly
Classification Name:	Accelerator, Linear, Medical
Regulation Number:	21 CFR 892.5050
Product Code:	IYE

Substantial Equivalence:

The Linac Collimator Assembly Housing (LCAH) is substantially equivalent in function and intended use with the XKnife Radiosurgery System (K912630) and the ARTISTE MV SA (K072485).

Indications Use:
The Integra Radionics™ Linac Collimator Assembly Housing (LCAH) is intended to be mounted as an Accessory tray for a LINAC to attach Integra Radionics collimators.

Device Description:

The Linac Collimator Assembly Housing (LCAH) consisting of a collimator sliding tray, collimator baseplate, and collimator tube. It is designed as a slide-in attachment for the Siemens MLC-160 LINAC Accessory Holder. The LCAH positions and aligns Radionics radiation beam shaping collimators to the Siemens ARTISTE LINAC (K072485) internal collimator and radiation source during radiosurgery and radiation therapy procedures.

Intended Users of the LCAH are medical physicists, radiation oncologists, and appropriate radiation technicians.

Conclusion:

The Linac Collimator Assembly Housing (LCAH) is substantially equivalent to the XKnife Radiosurgery System (K912630) and the Siemens ARTISTE MV SA (K072485). The Linac Collimator Assembly Housing (LCAH) is similar to the predicate devices in the intended use, the fundamental scientific technology of the device, and does not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Helder A. Sousa
Regulatory Affairs Project Manager
Integra Radionics, Inc.
22 Terry Avenue
BURLINGTON MA 01803

APR 22 2010

Re: K100096
Trade/Device Name: Linac Collimator Assembly Housing (LCAHART)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 15, 2010
Received: March 16, 2010

Dear Mr. Sousa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100096

Device Name: Linac Collimator Assembly Housing (LCAHART)

Indications For Use:

The Integra Radionics™ Linac Collimator Assembly Housing (LCAHART) is indicated to be mounted on the Siemens Artiste MV linac with MLC-160 Accessory Holder as an Accessory tray to attach Integra Radionics collimators for treatment modalities such as stereotactic radiosurgery (SRS) and radiotherapy (SRT).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100096